

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

THE MEDICINES COMPANY,)	
)	
)	
Plaintiff,)	
)	Case No. 11-cv-1285
v.)	
)	
)	
MYLAN INC., MYLAN)	
PHARMACEUTICALS INC., and)	
BIONICHE PHARMA USA, LLC,)	
)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

Before the Court is Plaintiff The Medicines Company's ("TMC") motion to compel testimony and production of information withheld on the basis of privilege by Defendant Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively, "Mylan"), pursuant to Federal Rule of Civil Procedure ("Rule") 37(a). (R. 225, Mot. to Compel.) Specifically, Plaintiff seeks production of (1) Mylan's expert, Dr. Fred E. Regnier, for a continuation of his deposition and (2) draft expert reports and attorney-expert communications related to Dr. Regnier's opening and reply expert reports. For the following reasons, the Court denies Plaintiff's motion to compel in its entirety.

BACKGROUND

I. Patents-in-Suit

Plaintiff TMC brought this lawsuit against Defendants, asserting that they infringed U.S. Patent Nos. 7,582,727 (the "727 Patent") and 7,598,343 (the "343 Patent," and collectively

with the '727 Patent, the "patents-in-suit"). The patents-in-suit pertain to pharmaceutical formulations of Bivalirudin and the processes of making Bivalirudin (the "New Process"). (R. 1, Compl.) Bivalirudin is the active ingredient in Angiomax®, an anticoagulant drug used in patients with unstable angina who are undergoing percutaneous transluminal coronary angioplasty. (*Id.* ¶¶ 11, 13.) TMC markets Angiomax®. (*Id.* ¶¶ 11, 13.)

TMC alleges that Mylan, before the expiration of the patents-in-suit, submitted Abbreviated New Drug Application ("ANDA") No. 202471 to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of its generic Angiomax® product. TMC avers that Mylan's ANDA No. 202471 infringes certain claims of the patents-in-suit.

In response to TMC's lawsuit, Mylan asserts, among others, a defense of inequitable conduct. (R. 185, Memo. Mot. to Compel at 1.) Mylan bases this defense on TMC's alleged deliberate failure to disclose highly material information to the United States Patent & Trademark Office ("PTO") during prosecution of the patents-in-suit. (*Id.*) Specifically, Mylan alleges that one of TMC's production batches of Bivalirudin—Lot No. 1344985—manufactured by Ben Venue Laboratories ("Ben Venue") violated a requirement of the patents-in-suit in that it contained a high level of the impurity Asp9. (*Id.* at 3.) The patents-in-suit claim the New Process produces Bivalirudin with a maximum Asp9 impurity level of 0.6% Asp9, but Mylan alleges that Lot No. 1344985, manufactured using the New Process, produced an Asp9 impurity level of 1.5% Asp9—150% higher than the maximum level recited in the patent claims. (*Id.* at 2–3; R. 199, Defs.' Reply at 5.) Mylan contends that TMC never disclosed the results of Lot No. 1344985 to the PTO. This failure serves as the basis for Mylan's inequitable conduct claim.

The Court presumes familiarity with the additional background of this litigation, and incorporates herein by reference the background information set forth in the Court's opinion dated August 6, 2012. (R. 119.)

II. Current Discovery Dispute

On February 8, 2013, Mylan's expert in high performance liquid chromatography ("HPLC"), Dr. Fred E. Regnier, served an opening expert report that included his opinions regarding the patents-in-suit. On March 8, 2013, TMC's expert, Dr. Alexander Klibanov, submitted a rebuttal report that responded to Dr. Regnier's opening report and then Dr. Regnier submitted a reply report on April 8, 2013. On April 26, 2013, counsel for TMC deposed Dr. Regnier. Prior to Dr. Regnier's deposition, TMC did not request Mylan to produce any additional documents relating to Dr. Regnier's expert reports. During the deposition, TMC's counsel interrogated Dr. Regnier regarding his opening report because it appeared to use language from a 2011 declaration in another case submitted by a different party's expert, Bernard A. Olsen, Ph.D. (the "Olsen declaration"). The Olsen declaration pertained to the same patents-in-suit involved in a case pending in the District of Delaware. *See The Medicines Company v. Teva Parental Medicines, Inc., et al.*, No. 09-cv-750-ER (D. Del.). In total, Dr. Regnier used approximately 4 to 5 pages of text from the Olsen declaration in his expert report that was 33 pages in length. The text appears to pertain to basic scientific principles that underlie HPLC. Dr. Regnier did not cite or quote the language from the Olsen declaration but did list the Olsen declaration as a document that he considered to formulate his opinions. (R. 234, Defs.' Response to Mot. to Compel at 9.) In addition, TMC's counsel alleges that Dr. Regnier also used language from Dr. David Auslander, another expert retained by Mylan, regarding the definition of a person of ordinary skill in the art ("POSA"). Dr. Regnier testified that Mylan's

counsel provided Dr. Regnier with a copy of the Olsen Declaration and communicated Dr. Auslander's definition of a POSA to him. (*Id.* at 8.) He testified, however, that the report states his opinions and that his opinions do not rely upon communications with Mylan's counsel. (*Id.* at 9.) During the deposition, Defendant Mylan's attorney instructed Dr. Regnier not to answer the inquiry of authorship, asserting work-product protection under Rule 26(b)(4).

At the end of Dr. Regnier's deposition, TMC asserted that the deposition would remain open and that TMC is entitled to testimony concerning authorship of Dr. Regnier's export report. On May 3, 2013, TMC's counsel requested Dr. Regnier for a second deposition as well as Dr. Regnier's draft reports and all associated communications between Dr. Regnier and Mylan's counsel. Mylan's counsel responded on May 6, stating that they were available to discuss the matter on the afternoon of May 7. TMC ignored Mylan's request and filed the motion to compel without conferral.

LEGAL STANDARD

This motion implicates standards that govern discovery as it relates to testifying experts. The Supreme Court amended Rule 26(b)(4), effective December 1, 2010, by adding Rule 26(b)(4)(B) to provide work product protection under Rule 26(b)(3)(A) and (B) for drafts of expert reports. Rule 26(b)(4)(C) extends work product protection to most communications between trial counsel and experts. Fed. R. Civ. P. 26(b).

Three exceptions apply to the protections afforded under Rule 26(b)(4)(C). First, attorney-expert communications that relate to expert compensation. Fed. R. Civ. P. 26(b)(4)(C)(i). Second, communications that identify facts or data that the party's attorney provided and that the expert considered in forming the opinions to be expressed. Fed. R. Civ. P. 26(b)(4)(C)(ii). Third, communications that identify the assumptions that the party's attorney

provided and that the expert relied upon in forming his opinions. Fed. R. Civ. P. 26(b)(4)(C)(iii). Discovery concerning attorney-expert communications on subjects outside the three exceptions as articulated above, or regarding draft expert reports or disclosures, is permitted only when a party makes a showing of substantial need and cannot obtain the substantial equivalent without undue hardship. Fed. R. Civ. P. 26(b)(3)(A)(ii). Further, when there is such a showing, the advisory committee notes show that “[i]n the rare case in which a party does make this showing, the court must protect against disclosure of the attorney’s mental impressions, conclusions, opinions, or legal theories under Rule 26(b)(3)(B).” Fed. R. Civ. P. 26(b)(3)(B) advisory committee’s note (2010). The Seventh Circuit instructs that in a motion to compel “a district court may grant or deny the motion in whole or in part, and similar to ruling on a request for a protective order under Rule 26(c), the district court may fashion a ruling appropriate for the circumstances of the case.” *Gile v. United Air Lines, Inc.*, 95 F.3d 492, 496 (7th Cir. 1996). As with all discovery matters, courts have broad discretion in determining motions to compel. *See James v. Hyatt Regency Chi.*, 707 F.3d 775, 784 (7th Cir. 2013); *Peals v. Terre Haute Police Dep’t*, 535 F.2d 621, 629 (7th Cir. 2008).

ANALYSIS

TMC contends that Mylan’s litigation counsel authored numerous sections of Dr. Regnier’s expert reports because they included language from the Olsen declaration and Dr. Auslander’s definition of POSA. Consequently, TMC seeks production of (1) Defendant’s expert, Dr. Regnier, for a continuation of his deposition and (2) draft expert reports and attorney-expert communications related to Dr. Regnier’s opening and reply expert reports. It argues that Rule 26 does not protect the aforementioned material from discovery because Mylan’s attorneys allegedly wrote the reports. In response, Mylan argues that: (1) TMC failed to comply with

Local Rule 37.2 and (2) Rule 26 does protect the documents and information from discovery.

The court agrees with Mylan.

I. Local Rule 37.2 (“L.R. 37.2”)

Before addressing the merits of TMC’s motion, Mylan argues that TMC elected not to meet and confer with Mylan’s counsel prior to filing its motion. Therefore, TMC failed to comply with Local Rule 37.2, which requires that “[t]o curtail undue delay and expense, this court shall hereafter refuse to hear any and all motions for discovery and production of documents under Rules 26 and 37” unless counsel has attempted to resolve differences and are unable to reach an accord. N.D. Ill. L.R. 37.2. TMC responds that the opposing counsel’s positions were made clear during Dr. Regnier’s deposition and that it filed this motion in view of Mylan’s refusal to provide the discovery sought. TMC has failed to comply with Local Rule 37.2. Given the numerous discovery disputes in the case, TMC certainly knows that the Court expects the parties to comply with this Rule in good faith. Despite TMC’s failure to do so, the Court nonetheless will address the merits of the motion given the posture of this case in order to avoid needless delay.

II. Rule 26 Protects the Documents and Information from Discovery

A. Work-Product Immunity under Amended Rule 26

Rule 26(b)(4)(B) provides work product protection under Rule 26(b)(3)(A) and (B) for drafts of expert reports, and Rule 26(b)(4)(C) extends work product protection to most communications between trial counsel and experts. Fed. R. Civ. P. 26(b)(4)(B)-(C).

Communications that relate to expert compensation or identify facts, data or assumptions that the party’s attorney provided, and that the expert considered and relied upon in forming the opinions to be expressed, are not precluded from discovery. Fed. R. Civ. P. 26(b)(4)(C)(i)-(iii).

Mylan argues that Rule 26 protects the draft expert reports and communications from discovery because TMC has failed to demonstrate that any of the three exceptions to the work product immunity apply. (R. 234, Defs.’ Resp. at 7.) The Court agrees.

The parties acknowledge that Dr. Regnier used language from the Olsen declaration in his expert report. Further, the parties acknowledge that Mylan’s counsel provided Dr. Regnier with the Olsen Declaration and that Dr. Regnier himself did not author the Olsen Declaration. (R. 227, Memo. Mot. to Compel. at 6, 9.) TMC does not allege that Mylan’s counsel authored the Olsen declaration, but they suggest that Mylan’s counsel copied language from the Olsen declaration and instructed Dr. Regnier to include that information in his expert report. (*Id.* at 12) The first and third exceptions to Rule 26(b)(4)(C) do not apply here because TMC is not concerned with information that relates to Dr. Regnier’s compensation or assumptions that Mylan’s counsel provided to Dr. Regnier. Instead, TMC argues that Rule 26 does not protect draft expert reports and attorney-expert communications related to Dr. Regnier’s opening and reply expert reports because it is entitled to “facts” that Mylan’s counsel may have provided to Dr. Regnier, including authorship of specific paragraphs. (R. 227, Memo. Mot. to Compel.) TMC’s assertion, however, is speculative at best and neither precedent nor the language of Rule 26 supports its assertion. As Mylan properly asserts, the types of documents and communications that TMC seeks are limited to those that identify “facts and data.” Any “further communications about the potential relevance of the facts or data” that may have been provided to Dr. Regnier are protected from discovery. Fed. R. Civ. P. 26 advisory committee’s note (2010). TMC heavily relies on a recent decision from the Oregon District Court in *Gerke v. Travelers Casualty Ins. Co.*, 289 F.R.D. 316 (D. Ore. 2013) in support of its position. Even if *Gerke* correctly applied Rule 26, *Gerke* is inapplicable to the facts of this case. Here, Mylan’s

counsel, unlike the defendant's counsel in *Gerke*, did not write any portion of the document that the counsel gave to the expert, Dr. Regnier. It is evident that Mylan's counsel in fact gave the Olsen declaration to Dr. Regnier for convenience and because it was written with respect to the same patents-in-suit. Additionally, a distinguished scholar such as Dr. Regnier is entitled to his own opinion regarding another expert's scientific opinion regarding the same patents-in-suit. *See Cimaglia v. Union Pacific R. Co.*, 586 F. Supp. 2d 1039, 1043 (C.D. Ill. 2008) (noting that an expert can review a previous expert's report and reach his own conclusion). Furthermore, Dr. Regnier testified that his opinions were his own opinions. The factual information he considered in Dr. Olsen's report pertained to HPLC and how it works. (R. 237. Ex. 7 at 257-59.) Dr. Regnier further explained that, based on his 40 years of experience in HPLC, he knows and understands HPLC independent of Dr. Olsen's declaration. (*Id.* at 258.) Of course, TMC may confront Dr. Regnier on cross-examination with the fact that portions of his report are identical to those of Dr. Olsen's declaration. The jury is free to decide what impact this similarity has on his credibility. *See Walden v. City of Chi.*, 755 F. Supp. 2d 942, 952-53 (N.D. Ill. 2010) ("[t]he question of whether the expert is credible or whether his or her theories are correct given the circumstances of a particular case is a factual one that is left for the jury to determine after opposing counsel has been provided the opportunity to cross-examine the expert regarding his conclusion and the facts on which they are based."); *see also Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 589-90 (7th Cir. 2000).

B. Substantial Need

The Court next turns to whether TMC has demonstrated a substantial need that may justify discovery of the requested documents and a continuation of Dr. Regnier's deposition. Discovery concerning attorney-expert communications on subjects outside the three exceptions

of Rule 26(b)(4)(C), or regarding draft expert reports or disclosures, is permitted only when a party makes a showing of substantial need and cannot obtain the substantial equivalent without undue hardship. Fed. R. Civ. P. 26(b)(3)(A)(ii). When there is such a showing, the advisory committee notes show that “[i]n the rare case in which a party does make this showing, the court must protect against disclosure of the attorney’s mental impressions, conclusions, opinions, or legal theories under Rule 26(b)(3)(B).” Fed. R. Civ. P. advisory committee’s note (2010). This is not one of those rare cases.

Mylan argues that Rule 26 protects the draft expert reports and communications from discovery and that TMC should not depose Dr. Regnier again because TMC has failed to demonstrate that there is a ‘substantial need.’ (R. 234, Defs.’ Resp. at 8.) The Court agrees.

Although TMC asserts that the author of Dr. Regnier’s export report is unknown and this factor may undermine Dr. Regnier’s credibility, these facts do not demonstrate a “substantial need” sufficient to overcome the work-product immunity attached to the draft reports and authorship information. TMC again cites the decision in *Gerke* to bolster its argument that there is a ‘substantial need.’ Again, however, *Gerke* is inapplicable to the facts here. Mylan, on the other hand, relies upon a recent decision from this District in *Sara Lee Corp. v. Kraft Foods, Inc.*, 273 F.R.D. 416 (N.D. Ill. 2011) that is applicable here. TMC, similar to the plaintiff in *Sara Lee*, examined Dr. Regnier’s report, deposed Dr. Regnier about his report, and retained its own expert to rebut the report. The fact that Mylan instructed Dr. Regnier to withhold authorship information does not change the fact that TMC had ample time and opportunity to question Dr. Regnier regarding his report and the opinions therein. In addition, TMC has the Olsen declaration and language from Dr. Auslander upon which Dr. Regnier relied. It is free to use this information to cross examine Dr. Regnier. TMC has failed to demonstrate that Mylan’s

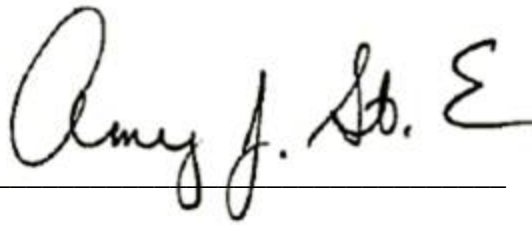
withholding authorship information constitutes a ‘substantial need’ sufficient to overcome work product immunity.

CONCLUSION

For the foregoing reasons, the Court denies Plaintiff TMC’s motion to compel in its entirety.

Date: June 13, 2013

ENTERED

A handwritten signature in black ink, reading "Amy J. St. Eve", written over a horizontal line.

AMY J. ST. EVE
United States District Court Judge